

b) placing said lens formulation in a lens mold;

c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyperm polymerizable material and said ionoperm polymerizable material of said lens formulation form separate oxyperm and ionoperm phases; said lens core material having an oxygen permeability equal to or greater than 69 barrers;

d) removing said lens core material from said lens mold;

e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and

f) hydrating the treated lens core material to produce a hydrated extended wear contact lens,

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as extended wear lens that is worn for a continuous period of at least 24 hours without having substantial amounts of lipid adsorption.

24. The method of claim 183 wherein the surface modification treatment is selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes.

25. The method of claim 183 wherein the surface modification treatment is a plasma treating process.

26. The method of claim 185 wherein said oxyperm polymerizable material is a fluorine macromer and said ionoperm polymerizable material is N-vinyl pyrrolidone.

27. An extended wear contact lens comprising a core polymeric material and upper and lower surfaces, said core polymeric material comprising a silicone copolymer which

provides a high ion permeability and a high oxygen permeability; said silicone copolymer comprising an oxyperm polymerizable material, and an ionoperm polymerizable material; said core polymeric material having an oxygen permeability equal to or greater than 69 barrers; wherein said surfaces are hydrophilically modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

B3
30

188. The extended contact lens of claim 187 wherein said core polymeric material comprises a fluorine macromer, and N-vinyl pyrrolidone.

31

189. The extended contact lens of claim 188 wherein said surfaces are modified by a plasma treating process.

32

190. The extended contact lens of claim 189 wherein said extended lens can be continuously worn for about 7 days with less than about 7 % corneal swelling.

33

191. The extended contact lens of claim 187 wherein said extended wear lens can be worn for about 30 days.

John C.
192. A hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having an oxygen permeability equal to or greater than 69 barrers, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion permeability, said core polymeric material having formed from polymerizable materials comprising:

- (a) an oxyperm polymerizable material, , and
- (b) an ionoperm polymerizable material,

wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that

Sub Cl

corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids, wherein said lens has an oxygen permeability of at least about 69 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater than about $6.4 \times 10^{-6} \text{ mm}^2/\text{sec}$ or an Ionoton Ion Permeability Coefficient of greater than about $0.4 \times 10^{-6} \text{ cm}^2/\text{min}$,

wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes,

wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

B3

35 193. The hydrogel contact lens of claim *192* wherein said core polymeric material comprises a fluorine containing macromer as said oxyperm material and N-vinyl pyrrolidone as said ionoperm material.

36 194. The hydrogel contact lens of claim *193* wherein said surfaces are modified by a plasma treating process.

37 195. The hydrogel contact lens of claim *194* wherein said lens can be worn for about 7 days in continuous contact with ocular tissues and fluids with less than about 8% corneal swelling.

38 196. The hydrogel contact lens of claim *194* wherein said lens is worn for about 7 days with less than about 4% corneal swelling.

39 197. The hydrogel contact lens of claim *194* wherein said lens can be continuously worn for about 30 days.

40 108. The hydrogel contact lens of claim 104 wherein said lens has an oxygen permeability of at least about 77 barrers. 36

41 109. A method of using a contact lens as an extended wear lens, said lens having ophthalmically compatible modified surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids, said lens comprising a polymeric material which has a high oxygen permeability and a high ion or water permeability, and which has an oxygen permeability equal to or greater than 69 barrers, said polymeric material being formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material, and
(b) an ionoperm polymerizable material,

wherein said modified surfaces are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes;

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids;

wherein said lens allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids without having substantial amounts of lipid absorption; and

wherein said ophthalmic lens has an oxygen permeability of at least about 70 barrers and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about $0.4 \times 10^{-6} \text{ cm}^2/\text{sec}$ or (2) an Ionoflux Diffusion Coefficient of greater than about $6.4 \times 10^{-6} \text{ mm}^2/\text{min}$, wherein said ion permeability is measured with respect to sodium ions;

said method comprising the steps of:

- (a) applying said lens to the ocular environment, and
- (b) allowing said lens to remain in continuous intimate contact with the ocular environment for a period of at least 24 hours without having substantial amounts of lipid adsorption.

42 200. The method of claim *199* wherein said lens has an oxygen permeability of at least about 77 barrers.

43 201. The method of claim *199* wherein said intimate contact period is at least 4 days.

44 202. The method of claim *199* wherein said intimate contact period is about 7 days.

45 203. The method of claim *199* wherein said intimate contact period is about 14 days.

46 204. The method of claim *199* wherein said intimate contact period is about 30 days.

47 205. The method of claim *199*, wherein said lens produces, after wear of about 24 hours, including normal steep periods, less than about 8% corneal swelling.

48 206. The method of claim *199*, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less than about 6% corneal swelling.

49 207. A method of forming a biocompatible lens having high oxygen permeability and high water permeability, said method comprising the steps of:

- (a) forming a polymeric core formulation comprising an oxyperm polymerizable material, and an ionoperm polymerizable material, said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of said lens formulation;
- (b) polymerizing the core in an atmosphere substantially free from oxygen;
- (c) altering the surface of said core material to produce a surface which is more hydrophilic than said core material; and
- (d) autoclaving lens at predetermined temperatures;

whereby said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids, and

whereby said lens allows ion permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said lens having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of contact for at least 24 hours,

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm²/sec or (2) by an Ionoflux Ion Permeability Coefficient of greater than about 1.5×10^{-6} mm²/min, wherein said ion permeability is measured with respect to sodium ions.

50
208. A method of forming a contact lens having high oxygen permeability and high water permeability, said method comprising:

(a) forming a polymeric core material in the shape of a contact lens having an inner and outer surface; and

(b) altering the surfaces of said core material to produce new surfaces that are more hydrophilic than said core material,

wherein said lens having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of contact for at least 24 hours.

51 *50*
209. The method of claim 208 wherein said intimate contact period is about 7 days.

52 50
210. The method of claim 208 wherein said intimate contact period is about 30 days.

53

50

211. The method of claim 208 wherein said lens is autoclaved at predetermined temperatures.

54

212. A biocompatible contact lens having high oxygen permeability and high water permeability, said lens comprising:

(a) a polymeric core material in the shape of a contact lens having an inner and outer surface; and

(b) said surfaces of said core material being surface modified to produce new surfaces that are more hydrophilic than said core material,

wherein said lens having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of contact for at least 24 hours.

55

54

213. The lens of claim 212 wherein said intimate contact period is at least 4 days.

56

55

214. The lens of claim 213 wherein said intimate contact period is about 7 days.

57

55

215. The lens of claim 213 wherein said intimate contact period is about 14 days.

58

55

216. The lens of claim 213 wherein said intimate contact period is about 30 days.

59

54

217. The lens of claim 212 including (c) said said lens being autoclaved at predetermined temperatures.

60

218. A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

a) preparing a lens formulation comprising an oxyperm polymerizable material, and an ionoperm polymerizable material, wherein said oxyperm

B3

polymerizable material comprises between about 30% to about 70%, based on the total weight, of said lens formulation;

- b) placing said lens formulation in a lens mold;
- c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyperm polymerizable material and said ionoperm polymerizable material of said lens formulation form separate oxyperm and ionoperm phases; said lens core material having an oxygen permeability equal to or greater than 69 barrers;
- d) removing said lens core material from said lens mold;
- e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and
- f) hydrating the treated lens core material to produce a hydrated extended wear contact lens,

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as extended wear lens that is worn for a continuous period of at least 24 hours without having substantial amounts of lipid adsorption.

61
219.

A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

- a) preparing a lens formulation comprising an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, fluorine-containing macromers and fluorine monomers, and an ionoperm polymerizable material, wherein said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of said lens formulation;
- b) placing said lens formulation in a lens mold;

B3

- c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyperm polymerizable material and said ionoperm polymerizable material of said lens formulation form separate oxyperm and ionoperm phases; said lens core material having at least one continuous pathway from said inner surface to said outer surface for oxygen transmission therethrough;
- d) removing said lens core material from said lens mold;
- e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and
- f) hydrating the treated lens core material to produce a hydrated extended wear contact lens,

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as extended wear lens that is worn for a continuous period of at least 24 hours with corneal swelling of less than about 8%.

62 220. The method of claim *219* wherein the surface modification treatment is selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes.

63 221. The method of claim *219* wherein the surface modification treatment is a plasma treating process.

64 222. The method of claim *221* wherein said oxyperm polymerizable material is a siloxane containing macromer or siloxane containing monomer and said ionoperm polymerizable material is N-vinyl pyrrolidone.

Sub Ch ~~223.~~ An extended wear contact lens comprising a core polymeric material and upper and lower surfaces, said core polymeric material comprising a silicone copolymer which provides a high ion permeability and a high oxygen permeability; wherein said silicone

Sub C1

~~copolymer comprises an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, siloxane-containing monomers, fluorine-containing macromers and fluorine-containing monomers, and an ionopermeable polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones, wherein said core polymeric material has at least one continuous pathway from said upper surface to said lower surface for oxygen treatment; wherein said surfaces are hydrophilically modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling.~~

B3

64 224. The extended contact lens of claim *223* wherein said core polymeric material comprises a siloxane-containing macromer or a siloxane monomer, and N-vinyl pyrrolidone. *65*

67 225. The extended contact lens of claim *224* wherein said surfaces are modified by a plasma treating process. *66*

68 226. The extended contact lens of claim *225* wherein said extended lens can be continuously worn for about 7 days with less than about 8 % corneal swelling. *67*

69 227. The extended contact lens of claim *224* wherein said extended wear lens can be worn for about 30 days. *66*

70 228. A hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having at least one continuous pathway between said surfaces for oxygen transmission therethrough, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion permeability, said core polymeric material having formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, siloxane-containing monomers, fluorine-containing macromers and fluorine-containing monomers, and

(b) an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones,

wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids, wherein said lens has an oxygen permeability of at least about 70 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater than about $6.4 \times 10^{-6} \text{ mm}^2/\text{sec}$ or an Ionoton Ion Permeability Coefficient of greater than about $0.4 \times 10^{-6} \text{ cm}^2/\text{min}$,

wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes,

wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling.

71
279. The hydrogel contact lens of claim 278 wherein said core polymeric material comprises a siloxane-containing macromer or a siloxane containing monomer as said oxyperm material and N-vinyl pyrrolidone as said ionoperm material.

72
280. The hydrogel contact lens of claim 279 wherein said surfaces are modified by a plasma treating process.

73
281. The hydrogel contact lens of claim 270 wherein said lens can be worn for about 7 days with less than about 8% corneal swelling.

74
282. The hydrogel contact lens of claim 270 wherein said lens is worn for about 7 days with less than about 4% corneal swelling.

75

23. The hydrogel contact lens of claim 230 wherein said lens can be continuously worn for about 30 days.

72

76 23. The hydrogel contact lens of claim 230 wherein said lens has an oxygen permeability of at least 75 days.

72

77

23. A method of using a contact lens as an extended wear lens, said lens having ophthalmically compatible modified surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids, said lens comprising a polymeric material which has a high oxygen permeability and a high ion or water permeability, and which has at least one continuous pathway between said modified surfaces for oxygen surfaces, said polymeric material being formed from polymerizable materials comprising:

- (a) an oxyperm polymerizable material, and
- (b) an ionoperm polymerizable material,

wherein said modified surfaces are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes;

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids;

wherein said lens allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids without having substantial amounts of lipid absorption; and

wherein said ophthalmic lens has an oxygen permeability of at least about 70 barrers and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.4×10^{-6} cm²/sec or (2) an Ionoflux Diffusion Coefficient of greater than about 6.4×10^{-6} mm²/min, wherein said ion permeability is measured with respect to sodium ions;

said method comprising the steps of:

(a) applying said lens to the ocular environment, and
(b) allowing said lens to remain in continuous intimate contact with the ocular environment for a period of at least 24 hours.

78
*23*6. The method of claim *235* wherein said lens has an oxygen permeability of at least about 77 barrers.

79
*23*7. The method of claim *235* wherein said intimate contact period is at least 4 days.

80
*23*8. The method of claim *235* wherein said intimate contact period is about 7 days.

81
*23*9. The method of claim *235* wherein said intimate contact period is about 14 days.

82
*23*10. The method of claim *235* wherein said intimate contact period is about 30 days.

83
*23*11. The method of claim *235*, wherein said lens produces, after wear of about 24 hours, including normal steep periods, less than about 8% corneal swelling.

84
*23*12. The method of claim *235*, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less than about 6% corneal swelling.

Remarks:

I. The Rejection of Claims 1 and 159-182 under 35 U.S.C. § 103(a) as being Unpatentable over Lai '461 or Lai '717 or Valint or Mueller each in view of Hofer or Lin or Sugiyama or Kiguchi is Error because One of Ordinary Skill In the Art Would Not be Motivated to Combine The Secondary References With The Primary References.

In the Office Action, the Examiner rejected claims 1 and 159 -182 by stating: